LEUKEMIA & LYMPHOMA SOCIETY®
fighting blood cancers

May 19, 2015

The Honorable Fred Upton
U.S. House of Representatives
Washington, D.C. 20515

The Honorable Frank Pallone
U.S. House of Representatives
Washington, D.C. 20515

The Honorable Joe Pitts
U.S. House of Representatives
Washington, D.C. 20515

The Honorable Gene Green
U.S. House of Representatives
Washington, D.C. 20515

The Honorable Diana DeGette
U.S. House of Representatives
Washington, D.C. 20515

RE: The 21st Century Cures Act

Dear Chairman Upton, Ranking Member Pallone, Chairman Pitts, Ranking Member Green, and Representative DeGette:

On behalf of the Leukemia & Lymphoma Society (LLS), I am writing to applaud the Energy & Commerce Committee for working with stakeholders to produce the bipartisan 21st Century Cures Act under consideration by the Committee. This landmark legislation will spur the discovery, development, and delivery of safe and effective therapies for the more than one million Americans fighting blood cancers today, as well as those who will be diagnosed with these cancers in the future.

LLS is dedicated to funding research across the continuum, from basic research through clinical trials, from bench to bedside. Since its inception, LLS has invested more than $1 billion in research to advance therapies and save lives. In fact, LLS research grants have funded many of today's most promising advances in cancer treatment, including therapies first approved for blood cancer patients that are now helping patients with other types of cancers and other serious diseases.

LLS commends the Committee for including in its legislation provisions that provide a pathway for robust patient involvement within the therapy development and approval processes. This measure will allow the Food and Drug Administration (FDA) to establish a structured framework for the meaningful incorporation of patient experience data into the regulatory decision making process. Empowering the patient voice during the discovery and development processes will accelerate patient access to new diagnostics, therapies, and cures that focus on what matters most to patients. LLS looks forward to helping the Committee advance these important patient engagement reforms as this bill advances through the legislative process.

LLS also applauds the inclusion of key provisions improving the expanded access process for providing access to investigational drugs. While a clinical trial can present an opportunity to be a part of the

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process to improve treatment options and increase survival, not every patient in this situation meets the requirements for an open trial. Fortunately, for these patients, the expanded access process can present a way for them to apply for access to an investigational treatment outside the scope of a clinical trial. The 21st Century Cures Act reforms will help patients and their doctors navigate the existing system for accessing investigational treatments, while also ensuring that the FDA provides the clarity necessary to encourage drug developers to provide appropriate access.

LLS appreciates the inclusion of several other provisions that will benefit blood cancer patients; including vital reforms to promote modern clinical trials and biomarker qualification; renewed investment in and focus on precision medicine; greater flexibility for FDA to hire, train, and retain expert review staff; and significant investment in the National Institutes of Health (NIH).

As the Committee contemplates this significant legislation, LLS thanks you for an inclusive process that has resulted in a package that promises to improve the quality of life for millions of Americans. We are eager to continue working with you and your staffs, and look forward to the day this legislation is enacted.

Sincerely,

Lisa Nelson
Vice President, Policy & Advocacy
The Leukemia & Lymphoma Society